REMARKS

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24, 26, 28-30, 33, 34, 36-38 and 40-43 are pending in this application. Claim 37 is amended. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claim are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather, the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the amendments should not give rise to any estoppel, as they are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 24, 26, 28-30, 33, 34, 36-38 and 40-43 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lisziewicz, Hope *et al.* and Riviere *et al.* The rejection is traversed.

Initially, it is noted that Lisziewicz and Hope have already been cited and overcome in the prosecution history of this application. On page 6 of the November 6, 2002 Office Action, in the context of withdrawing an obviousness rejection based on Lisziewicz, Hope and Naldini *et al.*, the Examiner stated that the claims are free of the prior art of record because the prior art does not teach or suggest a retroviral particle comprising a packageable retroviral RNA genome, which, when in the form of a DNA provirus, comprises a 5'LTR with tat inducible HIV U3 and R regions, a nucleotide sequence (NS) and polynucleotide response element (PRE), wherein the NS and PRE are located within an intron in a transcription unit of the provirus flanked by a retroviral splice donor (SD) site and splice acceptor (SA) sites derived from different retroviruses, and wherein the NS expression is undetectable in cells not expressing Tat and Rev genes. Now the Examiner has re-applied Lisziewicz and Hope under Section 103, newly combined with Riviere *et al.*

BEST AVAILABLE COPY

PAGE 6/8 * RCVD AT 10/12/2004 2:27:35 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/5 * DNIS:8729306 * CSID:12125880500 * DURATION (mm-ss):03-12

There is no teaching in any of the references that renders the claimed invention obvious. Lisziewicz, Hope or Riviere, alone or in combination, do not teach a truly Tat- and Rev-inducible retroviral vector, where there is no basal transcription in the absence of Tat and Rev. On the other hand, the claimed invention achieves a Rev-dependent intron by the placement of splice sites that flank an RRE-containing intron, and by the splice sites being derived from different retroviruses. Neither Lisziewicz, Hope nor Riviere discloses a retroviral vector having splice sites derived from different retroviruses.

The Office Action suggests that it is within the routine skill of the ordinary artisan to choose splice sites from different retroviruses for design of a retroviral vector that is Tat and Rev inducible. This is not the case. Inefficient splicing is the mechanism by which there is no detectable expression of the NS in cells lacking Tat and Rev. Inefficient splicing is a consequence of the placement and nature of the splice sites in the retroviral vector, *i.e.* placement of the splices sites around the intron, and recognition of the splices as being derived from different retroviruses. Therefore, inefficient splicing is inherently achieved by the limitations recited in the claims, and it is this feature that distinguishes the claimed invention from the prior art. No teaching in any of the cited references suggests or provides motivation to effect inefficient splicing with a retroviral vector. Accordingly, one of ordinary skill in the art would find no teaching or motivation in Riviere, or in the other cited references, to use splice sites from different retroviruses in a retroviral vector designed to be both Tat- and Rev- inducible.

Consequently, reconsideration and withdrawal of the rejection under Section 103 are requested.

III. THE REJECTION UNDER 35 U.S.C. §112, 1ST PARAGRAPH, IS OVERCOME

Claim 37 was rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. While Applicants disagree with the analysis set forth in the Office Action for reasons of record, claim 37 has been amended to recite that the polynucleotide response element (PRE) is an HIV Rev response element (RRE), in order to expedite prosecution. Applicants reserve the right to pursue the broader claims in continuing applications.

The claims meet the written description requirement and reconsideration and withdrawal of the rejection under Section 112 are requested.

PAGE 7/8 * RCVD AT 10/12/2004 2:27:35 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/5 * DNIS:8729306 * CSID:12125880500 * DURATION (mm-ss):03-12

PATENT
674523-2028

CONCLUSION

Applicants believe that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: _____
Thomas J. Kowalski
Reg. No. 32,147
(212) 588-0800

00224647

PAGE 8/8 * RCVD AT 10/12/2004 2:27:35 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/5 * DNIS:8729306 * CSID:12125880500 * DURATION (mm-ss):03-12

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.